

REMARKS

Claim status

Claims 1-20 were pending in the case at the time of the current Office Action. Claims 1, 5, 11, and 12 are amended herein to correct minor informalities. Claims 1-20 are currently pending in the application.

Section 112 rejections

In the current Office action, claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a preamplifier system circuit, does not reasonably provide enablement for amplifying a sensed signal by the preamplifier system circuit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the pacing system of the invention commensurate in scope with these claims. Paragraph [0021] describes the claimed method for determination of the presence of an evoked response includes the steps of amplifying the sensed signal by the preamplifier system of claims 1 or 4. Claims 1 and 4 do not provide an enabling disclosure for connecting the preamplifier system to sense signals.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

For a person skilled in the art, it is well known from the art that, for pacemakers, the sensed signals are provided by lead electrodes to the circuitry and that sensing occurs at the lead tip. This is also detailed in Fig. 1, Fig. 2, and Fig. 5 of the present application and explained in paragraphs [0028] and [0056] to [0061] of the present application. For example, the inputs 2, 3, and 43 shown in Fig. 2 may connect to electrodes 212 and 214 via electrode lead 210 as shown in Fig. 5. Moreover, claim 1 states: "...and sensing signals from the myocardium of multiple chambers of the heart...comprising: a preamplifier system circuit having at least two inputs for sensing signals to be picked up by at least two electrodes adapted to pick up the sensing signals, the preamplifier further comprises ...".

Therefore, in view of at least the foregoing, it is respectfully submitted that claims 1 and 4 do provide an enabling disclosure for connecting the preamplifier system to sensed signals, and it is respectfully submitted that claims 1 and 4 define allowable subject matter. Also, since claims 2-3 and 5-17 depend either directly or indirectly from one of claims 1 and 4, it is respectfully submitted that claims 2-3 and 5-17 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1-17 under 35 U.S.C. 112, first paragraph, be removed.

In the current Office action, claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by observing a programmable detection time window. An evoked response signal is claimed as triggering the threshold detector; however, antecedence is provided for a plurality of threshold detectors making it unclear which is being triggered.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Claims 12 and 19 have been amended herein to state "...triggering at least one threshold detector of the threshold detectors,". A predefined time interval (i.e., a detection time window) is observed for the presence of an evoked response signal. If an evoked response signal is detected within this time window (i.e., at least one threshold is exceeded), then at least one threshold detector is triggered.

Therefore, in view of at least the foregoing, it is respectfully submitted that the language of claims 12 and 19 is clear, and it is respectfully submitted that claims 12 and 19 define allowable subject matter. Applicants respectfully request that the rejection of claims 12 and 19 under 35 U.S.C. 112, second paragraph, be removed.

Section 102 rejections

In the current Office action, claims 1, 4, 5, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Whigham et al. (US 4,821,724), hereinafter Whigham.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a pacing system for pacing multiple chambers of the heart and sensing signals from the myocardium of multiple chambers of the heart which will allow the verification of a cardiac evoked response resulting from a delivered charge to the heart tissue comprising:

- a) a preamplifier system circuit having at least two inputs for sensing signals to be picked up by at least two electrodes adapted to pick up the sensing signals, the preamplifier further comprises
 - a) a DC coupled buffer amplifier first stage [emphasis added], comprising at least one buffer amplifier for each of the at least two electrode inputs,
 - b) a switch matrix [emphasis added] following the buffer amplifiers allowing sensing of the differential between any two of the at least two electrode inputs,
 - c) a next stage of differential amplifiers providing gain to either the differential between any two electrode inputs or one input to ground, and
 - d) a next stage filter stage.

Independent claim 4 recites a pacing system for pacing multiple chambers of the heart and sensing signals from the myocardium of multiple chambers of the heart which will allow the verification of a cardiac evoked response resulting from a delivered charge to the heart tissue, the pacing system having a pacing circuit capable of pacing multiple chambers of the heart, the pacing system comprising:

a preamplifier system having:

- a) a DC coupled buffer amplifier stage [emphasis added],

- b) a switch matrix [emphasis added] following the buffer amplifiers allowing sensing of the differential between any two electrodes implanted in the heart,
- c) a next stage of differential amplifiers providing gain to either the differential between any two electrode Inputs or one Input to ground, and
- d) a next stage wideband bandpass filter with gain, having an output and internal switches capable of discharging charges transferred across the Input allowing the output of bandpass filter to be reset to analog ground.

It is respectfully submitted that Whigham does not anticipate the claimed subject matter of independent claims 1 and 4. In particular, Whigham does not teach, suggest, or describe a DC coupled buffer amplifier and a switch matrix. According to Whigham, the input signals are directly directed to a differential amplifier. A DC coupled buffer amplifier does not exist in Whigham. Similarly, a switch matrix does not exist in the device of Whigham. The resistor network of Whigham is not equivalent to the switch matrix of the present application.

In the Examiner's response to arguments, the Examiner states that the amplifier 22 of Whigham is a DC coupled buffer amplifier and is used to block DC on the electrodes and to prevent the DC offset voltage of the amplifier 22 from being amplified. However, Applicants contend that an amplifier that blocks DC is not a DC coupled amplifier but is, instead, an AC coupled amplifier. By definition, a DC coupled amplifier does not block DC but, instead, passes DC. The amplifier 22 of Whigham is an AC coupled differential amplifier (i.e., coupled through a capacitor which blocks DC). The DC coupled buffer amplifier of the present application is not a differential amplifier and is not AC coupled. When amplifying sensed signals (mentioned in Whigham as ECG processing), amplifier 22 is operating as an AC coupled differential amplifier, not as a DC coupled buffer amplifier (see col. 9, line 48 to col. 10, line 9 and Fig. 5). Thus, no DC coupled buffer amplifier for sensing is disclosed in Whigham.

Furthermore, the resistor network having 288k resistors in combination with 144k resistors shown left in Fig. 2B serves as an attenuator which controls sensitivity (see col. 7, lines 1 to 17, Fig. 5 and Fig. 6). Whereas, the switch matrix of the present application is for selectively routing input signals originating from electrodes to differential amplifier inputs. For example, referring to Fig. 2 of the present application, the input signals coming into nodes 121

and 125 may be routed to any of the differential input node pairs 55 and 57, or 94 and 96, or 129 and 130, or 165 and 168. Input signals to the differential amplifier in Whigham originate from the same lead only (see explanation of dual chamber operation in col. 4, lines 58 to 68). Even if the choice of switching between the case or ring (in case of bipolar leads) as anode is disclosed, there is neither differential amplification of analog signals of different leads, nor differential amplification of more than two signals of the same lead in parallel possible. Whereas, in the present application, input signals to the differential amplifier may originate from any of the same or different leads controlled by the setting of the switch matrix.

A basic feature of the claimed subject matter of claims 1 and 4 is the possibility to evaluate different signals of different electrodes. This is only made possible by a combination of a DC coupled buffer amplifier and a switch matrix. Since these features are neither disclosed nor rendered obvious by Whigham, the claimed subject matter of claims 1 and 4 is neither anticipated nor rendered obvious by Whigham. Furthermore, in Whigham, only different signals of each one electrode may be evaluated. Whigham discloses to measure a signal between a tip and a ring electrode or a tip electrode and an implant's case, each for the similar electrode, but this cannot be done simultaneously by the device of Whigham.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claims 1 and 4 are not anticipated by Whigham, and it is respectfully submitted that claims 1 and 4 define allowable subject matter. Also, since claims 5 and 14 depend either directly or indirectly from one of claims 1 and 4, it is respectfully submitted that claims 5 and 14 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1, 4, 5, and 14 under 35 U.S.C. 102(b) be removed.

Section 103 rejections

In the current Office action, claims 2, 3, 6-13, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whigham.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 17 recites a method for operating a pacing system for verifying the capture of the myocardium, the method including the following steps:

- a) delivering a pacing pulse of programmable amplitude and pulse width,
- b) performing a first autoshort for a programmable time length,
- c) unblanking the amplifier system after the first autoshort and sensing an evoked response signal during a programmable sensing time window,
- d) amplifying the sensed signal by a preamplifier system having a DC coupled buffer amplifier first stage connected to a switch matrix [emphasis added],
- e) sending the amplified signal to the narrowband bandpass filter to allow passage of frequencies contained in the evoked response,
- f) comparing the signal from the band pass filter to a threshold value, and, if the signal exceeds the threshold value, generating a capture detected signal, and
- g) blanking the amplifier system at the end of the programmable sensing time window, and invoking the second autoshort for a programmable length of time.

Independent claim 18 recites a method for operating a pacing system for determining the presence of an evoked response of the myocardium, the method including the following steps:

- a) delivering a programmable stimulating monophasic pulse, followed by a programmable autoshort period which is shorter than the time between the end of the pace pulse and the beginning of an evoked response signal,
- b) opening switches connected to the input of buffer amplifiers [emphasis added] during the delivering of the pulse and the autoshort period, and closing the switches connected to the input of the buffer amplifiers immediately at the end of the autoshort period,

- c) at the same time during the delivering of the pulse and the autoshort period opening all blanking switches and setting all amplifier inputs in the filter stages to system ground,
- d) closing the matrix switches of the switch matrix [emphasis added] and placing sensed signals at the inputs of the differential amplifiers,
- e) closing the switch connecting the output of the differential amplifier to the fast high pass filter,
- f) discharging the charge transferred across the high pass capacitor to system ground, The output of the first high pass is then switched to a low pass filter,
- g) switching the signal to the next high pass filter,
- h) discharging the charge transferred across the high pass capacitor to system ground,
- i) sending the output of the second high pass stage to the final low pass filter,
- j) switching the output of the final low pass filter, to the bandpass filter stage, and
- k) connecting the outputs of the bandpass filters to programmable threshold detectors.

As stated previously herein, Whigham does not teach, suggest, or describe a DC coupled buffer amplifier and a switch matrix. According to Whigham, the input signals are directly directed to a differential amplifier. A DC coupled buffer amplifier does not exist in Whigham. Similarly, a switch matrix does not exist in the device of Whigham.

A basic feature of the claimed subject matter of claims 1, 4, 17 and 18 is the possibility to evaluate different signals of different electrodes. This is only made possible by a combination of a DC coupled buffer amplifier and a switch matrix. Since these features are neither disclosed nor rendered obvious by Whigham, the claimed subject matter of claims 1, 4, 17, and 18 is neither anticipated nor rendered obvious by Whigham. Furthermore, in Whigham, only different signals of each one electrode may be evaluated. Whigham discloses to measure a signal between a tip and a ring electrode or a tip electrode and an implant's case, each for the similar electrode, but this cannot be done simultaneously by the device of Whigham.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claims 1, 4, 17, and 18 are not unpatentable over Whigham, and it is respectfully submitted that claims 1, 4, 17, and 18 define allowable subject matter. Furthermore, since claims 2, 3, 6-13, 15-16, and 19-20 depend either directly or indirectly from on of claims 1, 4, 17, and 18, it is

respectfully submitted that claims 2, 3, 6-13, 15-16, and 19-20 define allowable subject matter as well. Applicants respectfully request that the rejection of claim 2, 3, 6-13, and 15-20 under 35 U.S.C. 103(a) be removed.

Accordingly, the applicant respectfully requests reconsideration of the rejections based on at least the foregoing. After such reconsideration, it is urged that allowance of all pending claims will be in order.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David J. Muzilla', is written over a horizontal line.

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